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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,250	07/30/2003	Stephen D. Pacetti	50623.267	9391

7590 12/23/2004

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EXAMINER

ZACHARIA, RAMSEY E

ART UNIT

PAPER NUMBER

1773

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/630,250

**Applicant(s)**

PACETTI ET AL.

**Examiner**

Ramsey Zacharia

**Art Unit**

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-24 and 26-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-24,26-43 and 54-99 is/are rejected.
- 7) ☒ Claim(s) 44-53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/01/2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

2. Claims 15 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 18-20 are rendered indefinite because it is unclear if the R and R<sub>1</sub> of the second polymer recited in claim 18 are identical to the R and R<sub>1</sub> recited in the first polymer of claim 18, chosen from the same group as those of claim 18, or are intended to have a separate definition.
4. Claim 15 recites the limitations "the aliphatic diol" and "the alkylene glycols" in lines 10 and 12, respectively. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 103***

5. Claims 1-4, 6-17, 21-24, 26-43, 54-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eury et al. (U.S. Patent 5,605,696) in view of Heller et al. (U.S. Patent 4,304,767).

Eury et al. is directed to a stent coated with a polymer component capable of carrying and releasing therapeutic drugs (column 1, lines 7-12). The polymer may be a polyorthoester (column 4, lines 37-54).

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Eury et al. do not teach the specific structure of the polyorthoester.

Heller et al. is directed to a polymer suitable for use as a drug carrier that may be used to fabricate articles such as implants (column 1, lines 10-20). The polymer comprises the reaction of a ketene acetal having a functionality of at least two with a polyol (column 2, lines 63-66). The ketene acetal may be a diketene acetal designated by Type I Monomers having a spiro structure in which the terminal R groups can be H or hydrocarbon groups (column 3, lines 25-55). This reads on the diketene acetal of formula (I) in instant claim 3. The polyol may be aliphatic diols, such as those having an alkylene chain of 2 to 12 carbon atoms (column 6, lines 52-67). The polyol may be a polyglycol, such as diethylene glycol or triethylene glycol (column 7, lines 13-20). The polyol may be cycloaliphatic diols, such as *cis* and *trans* cyclohexane diols and cyclobutane diol (column 7, lines 21-34). The polyol may also be an aromatic diol, such as 1,4-dihydroxymethylbenzyl (i.e. p-benzenedimethanol) (column 7, lines 46-66).

Regarding the numerous individual species of diols recited in the instant claims the compounds recited in these claims have very close structural similarities and utilities to those taught by Heller et al. For example, while Heller et al. may not explicitly recite each and every aliphatic diol, not only do Heller et al. teach the broad class of aliphatic diol and but numerous specific examples are provided. As such, a *prima facie* case of obviousness exists based on the similarity in chemical structure and function between the disclosed genera and species of Heller et al. and those recited in the instant claims since there is an expectation that compounds similar in structure will have similar properties. See MPEP § 2144.09.

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*Allowable Subject Matter*

6. Claims 18-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the reasons put forth in the action mailed 20 July 2004.

7. Claims 44-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter.

Claims 44-53 are directed to a medical article comprising an implantable substrate having a coating deposited thereon. The coating comprises the polymer product of a co-condensation reaction of a diketene acetal, a diol, and a hydroxylated functional compound. For each of the claims, the diol is as defined in claim 1. The hydroxylated functional compound is as recited in each of claims 44-53.

Eury et al. and Heller et al. represent the closest prior art. However, neither Eury et al. nor Heller et al. teach or fairly suggest the use of a co-condensation polymer formed from three separate components: a diketene acetal, a diol as claimed, and the hydroxylated functional compound of claims 44-53.

*Response to Arguments*

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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However, in response to the applicants' assertion that one of ordinary skill in the art would recognize that polymers made of components with similar structures may not necessarily have similar properties, this is not persuasive for at least the reason that Heller et al. disclose a broad array of suitable diols. Therefore, Heller et al. suggests to one skilled in the art the interchangeability of any of the broadly recited diols as well as the expectation that diols having similar chemical structures will have similar properties.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

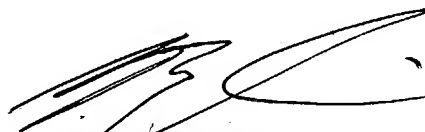
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday through Friday from 9 to 5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached on (571) 272-1535. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Ramsey Zacharia**  
**Primary Examiner**  
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